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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,668	01/16/2004	Don W. Lee	003-18	8616
7590 11/17/2005				
James E. Brunton, Esquire Post Office Box 29000 Glendale, CA 91209-9000			EXAMINER WILLIAMS, KENNETH C	
			ART UNIT 3739	PAPER NUMBER

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/759,668

Applicant(s)

LEE, DON W.

Examiner

Kenneth C. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 6, 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 7, 8 and 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 November 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I: Figures 1-3

Species II: Figures 4-6

Species III: Figures 7-9

Species IV: Figures 12-14

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with James Brunton on 10/25/05 a provisional election was made without traverse to prosecute the invention of Species I, claims 1,2,5,7,8 and 11-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3,4,6,9 and 10 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "39" has been used to designate both guide wire opening and electronic means. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: distal end, element 22. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claim 16 is objected to because of the following informalities: Line 6 of the claim recites "said passageway". It is uncertain as to the passageway to which reference is made. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1,2,5,7,8,11-13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Carberry (U.S. Patent Application No. 20050171437).

a. In regards to Claims 1,7 and 13, Carberry meets all of the limitations of the claims including: a guide wire (Paragraph 0030), a catheter (Paragraph 0030), a first passageway (Paragraph 0033), a second passageway (Paragraph 0033), an energy transmission means (Figure 1, element 130), a source of energy (Figure 1, element 102), detector means (Figure 1, element 122), electronic means (Figure 1, element 120), and display means (Figure 5, element 520).

b. In regards to Claims 2 and 8, Carberry discloses a catheter system comprising "said outer side wall of said catheter is provided with an opening in communication with said first passageway for receiving said guide wire therethrough" (See Figure 2; see also Paragraph 0030).

c. In regards to Claims 5 and 11, Carberry discloses a catheter system comprising "said source of energy comprises a low coherence light source" and "said illumination means comprises a low coherence light source" (See Paragraph 0028).

d. In regards to Claim 12, Carberry discloses a catheter system comprising "said reflecting means comprises a mirror" (See Paragraph 0041).

- e. In regards to Claim 15, Carberry discloses a catheter system comprising "said catheter has an axial center line and in which said first and second passageways are radially off set from said axial centerline" (See Figure 4).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carberry (U.S. Patent Application No. 20050171437) in view of Auer et al. (U.S. Patent No. 5383467).

In regards to Claim 14, Carberry discloses a catheter system having a guide wire (See Claim 13 Rejection). Carberry remains silent as to the diameter of its guide wire. Attention is directed to the Auer et al. reference, which in an analogous field of endeavor discloses a guide wire catheter with an outer diameter of approximately 0.014 inches (See Auer et al. column 5, lines 20-24). Therefore, it would have been obvious to

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one of ordinary skill at the time of the invention to use a guide wire of the diameter claimed in the catheter system of Carberry in light of the teaching of Auer et al. that such guide wires are known for use in a vascular catheter.

11. Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carberry (U.S. Patent Application No. 20050171437) in view of Winston et al. (U.S. Patent No. 5951482).

a. In regards to Claims 16 and 18, Carberry discloses a method comprising "a guide wire having first and second ends, a catheter having a distal end and a proximal end, a first passageway through which the guide wire can be slideably moved, a second passageway spaced apart from said first passageway, and an optical coherence reflectometry system including an optical fiber received with in said passageway" (See Carberry Paragraphs 0030-0036). Carberry does not disclose the method as recited in the claim. Attention is directed to the Winston et al. reference, which in an analogous field of endeavor discloses a method of opening an occlusion utilizing a guide wire and an optical fiber (See Winston et al. column 3, lines 1-44). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Carberry with the teaching of Winston et al. in order to open an occlusion as well as monitor the direction of the catheter in proximity to the arterial wall.

b. In regards to Claims 17 and 19, Carberry in view of Winston et al. discloses a method (See Claim 16 or Claim 18 Rejection). Carberry does not disclose the method as recited in claims 17 and 19. Attention is directed to the

Winston et al. reference, which in an analogous field of endeavor discloses a method of advancing a guide wire through an occlusion and an optical fiber to monitor catheter distance from the arterial wall (See Winston et al. column 3, lines 1-62). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Carberry with the teaching of Winston et al. in order to open an occlusion as well as monitor the direction of the catheter in proximity to the arterial wall.

c. In regards to Claim 20, Carberry in view of Winston et al. discloses a method (See Claims 19 Rejection). Carberry further discloses "the further step of removing the guide wire and the catheter from the artery". Carberry inherently is capable of meeting this limitation.

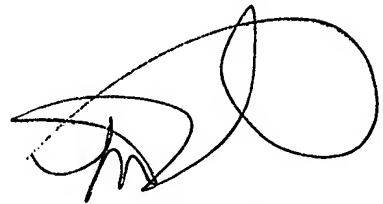
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth C. Williams whose telephone number is (571) 272-8161. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KCW

A handwritten signature in black ink, appearing to read 'Linda C. M. Dvorak', with a large, stylized loop at the end.

LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700